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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/720,086 | 07/23/2001 | En Li | 0609.4560002 | 6968 |
| 26111 | 7590 | 09/06/2006 | EXAMINER | |
| STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005 | | | HARRIS, ALANA M | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1643 | | |

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/720,086 | LI ET AL. | |
| | Examiner | Art Unit | |
| | Alana M. Harris, Ph.D. | 1643 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 June 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3-10,13 and 25-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1, 3-10, 13, and 25-50 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Response to Arguments

1. Claims 1, 3-10, 13 and 25-50 are pending.

Claims 1, 3-10, 13 and 25-50 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

3. There is sufficient proof that the proper sequences in the instant application and corresponding clones are one in the same as those listed in the priority documents, see Declarations submitted November 7, 2005. The priority afforded claims 1, 3-10, 13 and 25-50 is June 25, 1998.

Withdrawn Objection

Specification

4. The drawings originally filed with the specification are no longer objected to under 35 U.S.C. 132 because of the reason set forth in the Priority section of the instant Action.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

5. The rejection of claims 25-28, 32-35 and 45-48 under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement commensurate with the scope of the claimed invention is withdrawn in light of Applicants' arguments.

Claim Rejections - 35 USC § 102

6. The rejection of claims 1, 3-9 and 25-50 under 35 U.S.C. 102(b) as being anticipated by Okano et al. (Nature Genetics 19:219 and 220, July 19, 1998), as evidenced by Accession numbers AF068625, AF068626 and AF068627 (December 6, 1999) is withdrawn in light of the newly afforded priority date, June 25, 1998.

7. The rejection of claims 1, 3-9 and 25-50 under 35 U.S.C. 102(b) as being anticipated by Xie et al. (Gene 236(1): 87-95, 1999), as evidenced by Accession number AF067972 (February 12, 2001) is withdrawn in light of the newly afforded priority date, June 25, 1998.

Claim Rejections - 35 USC § 103

8. The rejection of claims 1, 3-9, 13 and 25-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Okano et al. (Nature Genetics 19:219 and 220, July 19, 1998), as evidenced by Accession numbers AF068625, AF068626 and AF068627

(December 6, 1999), and in view of U.S. Patent 6,492,168 B1 (April 22, 1998) is withdrawn in light of the newly afforded priority date, June 25, 1998.

9. The rejection of claims 1, 3-9, 13 and 25-50 under 35 U.S.C. 103(a) as being unpatentable over Xie et al. (Gene 236(1): 87-95, 1999), as evidenced by Accession number AF067972 (February 12, 2001), and in view of U.S. Patent 6,492,168 B1 (April 22, 1998) is withdrawn in light of the newly afforded priority date, June 25, 1998.

Double Patenting

10. The provisional rejection of claims 8-10 and 13 under 35 U.S.C. 101 as claiming the same invention as that of claims 51-55 of copending Application No. 10/623,813 (filed July 22, 2003) is withdrawn in light of Applicants' arguments.

Maintained Rejections

Claim Rejections - 35 USC § 112

11. The rejection of claims 1, 3-10, 13, 29-31, 36-44, 49 and 50 under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement commensurate with the scope of the claimed invention is maintained.

Applicants assert the Examiner has taken contradictory positions and "Applicants believe one of ordinary skill in the art would be able to make and use the nucleic acid molecules... without undue experimentation.", see Remarks, pages 16-20. These points of view have been carefully considered, but found unpersuasive.

The Examiner does not concur with Applicants' position. At this point in prosecution the claims read on isolated nucleic acid molecules, which have limited or reduced sequence identity to "wild-type" molecules. These variant molecules are claimed to encode polypeptides capable of methylating DNA in an *in vitro* assay. By virtue of the language "capable" there is not assuredness that these mutant molecules will indeed do as the claims assert. And while one of ordinary skill in the art can make polynucleotides with at least 90% sequence identity and polynucleotide sequences complementary to polynucleotides listed in sections a-e of claims 1 and 31 there is no guidance on how and those complementary sequences would be anti-sense sequences which would not encode a polypeptide. Moreover, the specification does not provide sufficient guidance for implementing the method of claim 13 with a mutant polypeptide encoded by a nucleic acid of claim 1 in particular those of sections e and f of claim 1. Given the insufficient guidance, the changes which must be made in the nucleic acid sequences of SEQ ID NO: 1-4, which results in nucleic acid sequences with 90% identity and sequences that are complementary to the coding sequences and the implementation of the claimed polynucleotide sequences is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue.

12. The rejection of claim 10 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

Applicants assert "...the specification discloses the range of fragment sizes by a mathematical formula" and the Examiner seems to require the claimed subgenus be described in *ipsis verbis*, see Remarks, page 21, 1st paragraph. Applicants continue to assert person of ordinary skill would envision each and every fragment size in view of the formula because the fragment size is the only variable. These points of view and arguments have been carefully considered, but found unpersuasive.

Applicants' specification is still remiss of sufficient information, guidance and sincere contemplation of an oligonucleotide probe or primer at least 100 contiguous nucleotides in length. Applicants' position is that a skilled artisan would readily arrive at the contemplation of at least 100 contiguous nucleotides of SEQ ID NO: 3. The Examiner does not concur and does not note significant information that leads the skill artisan to such contemplation. Consequently, the rejection is maintained.

Double Patenting

13. The provision rejection of claims 1, 3-7 and 25-50 under 35 U.S.C. 101 as claiming the same invention as that of claims 51-55 of copending Application No. 10/623,813 (filed July 22, 2003) is maintained.

Applicants argue the deposits listed in claims 51-55 are different from the Dnmt3a sequences in that they are shorter isoforms and are not coextensive in scope with the instant application's claims. This argument has been carefully considered, but found unpersuasive.

Applicants have not supplied corresponding SEQ ID numbers for these deposits and consequently it is difficult to assess which sequences are different from the others. For the reasons of record the rejection is maintained.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone

Art Unit: 1643

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.

PRIMARY EXAMINER


Alana M. Harris, Ph.D.
5 September 2006